

**REMARKS**

Claims 55-64 were pending in the instant application. Claims 16-54 were previously withdrawn from consideration and claims 1-15 were previously canceled by Amendment. By this Amendment, Applicant has canceled claims 16-54 and 60-62 without prejudice to the right to file further divisional or continuation applications. Applicant has presented the subject matter of claims 60-62 in new claims 65-67, all of which now ultimately depend from claim 55. Support for the new claims can be found in the specification and in the claims as originally filed. Specifically, support can be found, *inter alia*, in original claims 1-8 and in Figures 1-4. The new claims do not introduce any new matter, and thus, their entry is requested. Applicant further points out that the present Amendment follows a telephone interview held July 2, 2003 between Applicant's undersigned attorney, Patrick T. Skacel, and Examiner Goldberg. The remarks presented in this Amendment make of record and further address the issues discussed during the interview. Upon entry of the present Amendment, claims 55-59 and 63-67 will be pending and under examination.

**The March 25, 2003 Final Office Action**

In the March 25, 2003 Office Action, the Examiner asserted that the new claims presented in Applicant's December 23, 2002 response included subject matter that was not previously examined or searched. Consequently, the Examiner indicated that the claims were being withdrawn in part, as being directed to a non-elected invention. Specifically, the Examiner first indicated that claims 60-62 encompassed a combination of genes beyond those which were included in the originally elected claims. According to the Examiner, the original claims were directed to at least one gene

from TPH, PNMT, ADOA2A, NOS3 and NAT1, while the new claims now also encompassed ADRA2A, ADRA2C, NET, COMT, CHRNA, both individually and in combination. The Examiner thus indicated that claims 60-62 would be withdrawn in part.

The Examiner further asserted that new claims 55-59 and 63-64 were drawn to a generic method which was not previously examined or searched and which included distinct method steps from those in previously examined claim 9, on which claim 55 was based. The Examiner explained that in her opinion, claims 55-59 and 63-64 also were patentably distinct from claims 60-62 because "they each have different objectives, different uses, different reagents and different method steps." The Examiner stated that the method of claims 60-62 determine whether a subject is at risk for ADHD by determining the presence of particular polymorphisms, while the method of claims 55-59 and 63-64 determine whether genes contribute to ADHD by performing detailed statistical analysis for a combination of genes. The Examiner thus withdrew claims 55-59 and 63-64 from consideration as directed to a non-elected invention.

Examiner's Rejection of claims 60-62 Under 35 U.S.C. §112,  
first paragraph - Enablement

The Examiner rejected claims 60-62 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection essentially repeats the previous rejection of claims 1-15, set forth in the July 22, 2002 Office Action.

Specifically, the Examiner stated that it was still unclear how the data should be interpreted in that some genes appeared in the Figures to be both significant and not significant in their

contribution to the recited disorder. The Examiner particularly noted apparent confusion between Figure 3 and Figure 1. The Examiner also stated that the art appears to reflect association between certain polymorphisms and ADHD in some populations but not in others.

Based on the Examiner's interpretation of the data, the Examiner then concluded that the claims directed to determining risk of ADHD were not enabled for all non-wild type alleles, asserting that the specification does not disclose a representative number of polymorphisms from the recited genes.

July 2, 2003 Telephone Interview

In the July 2, 2003 interview, Applicant's attorney and Examiner Goldberg first discussed pending rejected claims 60-62. The Examiner reiterated her position that it was unclear how one would be able to determine that a subject was at risk for ADHD simply by determining whether that subject's genome comprised a particular polymorphism in a gene, given that the art and some of the data in the specification appeared to indicate that the gene was not significant in its contribution to the disorder.

Applicant's attorney explained that prior art methods for determining risk were not adequate because they did not take into account the additive effect of multiple genes in studying polygenic disorders. Thus, prior art methods could appear to indicate that some genes are not significant in their contribution to ADHD, when in fact the genes are significant as shown by the superior methods of the Applicant's claimed invention. Applicant's attorney explained that it appears to be this difference in results, which is reflected in the data included in the specification, that is accounting for the Examiner's conclusion that the data appears inconsistent.

Applicant's attorney further explained that the Applicant's superior method was that method reflected in claims 55-59 and 63-64 (which represent a clarification of the method of original claim 9). It is this method which was used to determine that the specific genes of claims 60-62 are in fact significant in their contribution to ADHD. In response, the Examiner pointed out that claim 60 did not include the steps of claim 55, and thus was a distinct method.

The Examiner then indicated, however, that she would be willing to permit the Applicant to shift the invention to include claims directed to the method reflected in claims 55-59 and 63-64, upon Applicant's filing of a Request for Continued Examination (RCE).

In response, Applicant appreciates the Examiner's willingness to examine claims directed to the method previously indicated to be withdrawn from consideration, upon Applicant's filing of an RCE. Applicant is thus concurrently filing an RCE as suggested by the Examiner and requesting by this Amendment that the Examiner proceed to examine previously presented claims 55-59 and 63-64 (along with new claims 65-67).

With respect to the rejection of claims 60-62 under 35 U.S.C. §112, first paragraph, Applicant has canceled these claims and presented new claims 65-67 in their place. The new claims now depend from claim 55, and therefore incorporate the method steps included therein. Applicant believes that the presentation of these new claims to include the subject matter indicated by the Examiner to be absent, overcomes the enablement rejection of claims 60-62 as set forth in the March 25, 2003 Office Action and reiterated by the Examiner in the telephone interview. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the enablement rejection.

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In view of the above remarks, and the presentation of new claims 65-67, Applicant asserts that all pending claims, namely 55-59 and 63-67 represent a single invention and are fully enabled. Applicant further believes that the present application is in condition for allowance and respectfully requests reconsideration of the application and early notice of allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite prosecution of the application.

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